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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,276	10/20/2003	Daniel Cimbora	1834.01	8598

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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/690,276	Applicant(s) CIMBORA ET AL.	
	Examiner Jon M. Lockard	Art Unit 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3 (each in part), 4-5, and 11-12 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering a peptide having a contiguous amino acid sequence of ERK3 which binds PRAK, classified in class 435, subclass 7.8, for example.
  - II. Claims 1-3 (each in part), 6-7, and 11-12 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering a peptide having a contiguous amino acid sequence of PRAK which binds ERK3, classified in class 435, subclass 7.8, for example.
  - III. Claims 1-3 and 8 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering an antibody that binds PRAK, classified in class 435, subclass 7.1, for example.
  - IV. Claims 1-3 and 8 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering an antibody that binds ERK3, classified in class 435, subclass 7.1, for example.
  - V. Claims 1-3 and 9 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering a nucleic acid that encodes an antibody that binds PRAK, classified in class 514, subclass 44, for example.

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- VI. Claims 1-3 and 9 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering a nucleic acid that encodes an antibody that binds ERK3, classified in class 514, subclass 44, for example.
- VII. Claims 1-3 and 10 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering an antisense and/or ribozyme that binds a nucleic acid encoding PRAK, classified in class 514, subclass 44, for example.
- VIII. Claims 1-3 and 10 (each in part), in so far as they are drawn to a method for modulating interaction of ERK3 with PRAK comprising administering an antisense and/or ribozyme that binds a nucleic acid encoding ERK3, classified in class 514, subclass 44, for example.
- IX. Claims 13-14 (each in part) and 15-16, drawn to a method of treatment comprising administering a peptide having a contiguous amino acid sequence of ERK3 which binds PRAK, classified in class 514, subclass 2, for example.
- X. Claims 13-14 (each in part) and 17-19, drawn to a method of treatment comprising administering a peptide having a contiguous amino acid sequence of PRAK which binds ERK3, classified in class 514, subclass 2, for example.
- XI. Claims 5, 13, and 20 (each in part), in so far as they are drawn to a method of treatment comprising administering an antisense and/or ribozyme that binds a nucleic acid encoding PRAK, classified in class 514, subclass 44, for example.

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XII. Claims 5, 13, and 20 (each in part), in so far as they are drawn to a method of treatment comprising administering an antisense and/or ribozyme that binds a nucleic acid encoding ERK3, classified in class 514, subclass 44, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I-XII are directed to methods that are distinct both physically and functionally, have different method steps, starting compounds, and goals, and are not required one for the other.

4. Invention I requires search and consideration of administering a contiguous amino acid sequence of ERK3 to a host cell, which is not required by any of the other Inventions. Invention II requires search and consideration of administering a contiguous amino acid sequence of PRAK to a host cell, which is not required by any of the other inventions. Invention III requires search and consideration of administering an antibody that binds PRAK to a host cell, which is not required by any of the other inventions. Invention IV requires search and consideration of administering an antibody that binds ERK3 to a host cell, which is not required by any of the other inventions. Invention V requires search and consideration of administering a nucleic acid that encodes an antibody that binds PRAK to a host cell, which is not required by any of the other inventions. Invention VI requires search and consideration of administering a nucleic acid that encodes an antibody that binds ERK3 to a host cell, which is not required by any of the other

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inventions. Invention VII requires search and consideration of administering an antisense and/or ribozyme that binds a nucleic acid encoding PRAK to a host cell, which is not required by any of the other inventions. Invention VIII requires search and consideration of administering an antisense and/or ribozyme that binds a nucleic acid encoding ERK3 to a host cell, which is not required by any of the other inventions. Invention IX requires search and consideration of treatment comprising administering a peptide having a contiguous amino acid sequence of ERK3, which is not required by any of the other inventions. Invention X requires search and consideration of treatment comprising administering a peptide having a contiguous amino acid sequence of PRAK, which is not required by any of the other inventions. Invention XI requires search and consideration of treatment comprising administering an antisense and/or ribozyme that binds a nucleic acid encoding PRAK, which is not required by any of the other inventions. Invention XII requires search and consideration of treatment comprising administering an antisense and/or ribozyme that binds a nucleic acid encoding ERK3, which is not required by any of the other inventions. Therefore, each method is divergent in materials and steps. For these reasons, Inventions I-XII are patentably distinct. Furthermore, the distinct steps and products require separate and distinct, non-coextensive searches. The inventions of Groups I-XII have a separate status in the art as shown by their separate search requirements. As such, it would be burdensome to search the inventions of Groups I-XII together.

5. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their separate search requirements, each group requires a

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different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

***Election of Species***

6. In addition to the above Restriction Requirements, a further election of species is required as follows:

***If Applicants elect Inventions I, II, or X***

7. This application contains claims directed to the following patentably distinct species of the claimed invention: each of the transporters listed in claim 12 or 19. Each transporter represents a patentably distinct species of chemical compound, having different structures, different classification, and requiring separate searches. Search of more than one compound would constitute a burden on the Office.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 11, 13, and 17 are generic.

9. Applicant is advised that a reply to this requirement must include an identification of the single species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**If Applicants elect Invention IX, X, XI, or XII**

12. This application contains claims directed to the following patentably distinct species of the claimed invention: each of the diseases/disorders set forth in claim 13. Each disease or disorder is considered to be a patentably distinct species because they have different etiologies, symptoms, and physiological results, and would require separate search and consideration. Furthermore, search of more than one disorder or condition would constitute a burden on the Office.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.



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15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML  
December 28, 2005

*Bridget E. Bunner*

**BRIDGET BUNNER  
PATENT EXAMINER**